UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION	MDL No. 2642 (JRT)
THIS DOCUMENT RELATES TO: *Jennifer Akman v. Bayer Health Care Pharmaceuticals, Inc., Cobalt Laboratories, Inc. AKA Cobalt Laboratories LLC,* and *Actavis Pharma Co.* Case No. 0:17-cv-00260-JRT.	**MEMORANDUM OPINION AND ORDER GRANTING JUDGMENT ON THE PLEADINGS AND GRANTING LEAVE TO AMEND THE COMPLAINT** Master Docket Case No. 0:15-md-02642

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Defendants Cobalt Laboratories and Actavis Pharma, succeeded by Teva Canada, manufacturers of generic ciprofloxacin, filed a Motion for Judgment on the Pleadings asking the Court to dismiss Plaintiff Jennifer Akman's case because her claims under District of Columbia law are preempted by federal law. Plaintiff Akman argues that her claims, related to injuries caused by ciprofloxacin, are not preempted and, in the alternative, asks for leave to amend. The Court finds that Akman's D.C. law claims based

on Generic Defendants' failure to update their pharmaceutical product information to match FDA-approved warnings are not facially preempted by federal law. But because Akman has not pleaded sufficient allegations or explanations of the source of her claims under D.C. law, the Court will grant Akman leave to amend her complaint.

BACKGROUND

In November 2013, Plaintiff Jennifer Akman was prescribed Cipro or its generic equivalent, ciprofloxacin. (Notice of Removal, Ex. A ("Compl.") ¶ 15, Jan. 17, 2017, Docket No. 1-1.) Akman stopped taking the medication within 24 hours because of a severe adverse reaction. (Compl. ¶ 16.) Akman continues to suffer nerve damage and other injuries from the medication. (*Id.* ¶ 18.)

On November 15, 2016, Akman filed a Complaint against Bayer Healthcare Inc., Bayer Corporation,[1] Cobalt Laboratories, Inc. AKA Cobalt Laboratories LLC ("Cobalt"), and Actavis Pharma Company, succeeded by Teva Canada ("Teva"), in the Superior Court of the District of Columbia (the "Initial Complaint"). (*Id.* ¶¶ 5–14.) Defendants Cobalt and Teva (collectively, "Generic Defendants"), are manufacturers of generic pharmaceutical products, including ciprofloxacin. (*Id.* ¶ 13–14.) Akman alleges that, on August 15, 2013, the FDA issued an updated warning about the risk of peripheral neuropathy from use of Cipro and ciprofloxacin, but Generic Defendants had not updated their labels and other

[1] The Bayer Defendants were dismissed from the case pursuant to a stipulation of dismissal on November 9, 2019. (Order Stip. Dismissal, Nov. 19, 2019, Docket No. 28.)

product information in compliance with the August 2013 mandate at the time Akman was prescribed ciprofloxacin in November 2013. (*Id.* ¶¶ 53–55; *see also id.* ¶¶ 95, 102, 121.)

The case was removed to the U.S. District Court for the District of Columbia on January 17, 2017, (Notice of Removal, Jan. 17, 2017, Docket No. 1), and then transferred to the District of Minnesota on January 27, 2017 to be consolidated for pretrial proceedings as part of *In re: Fluoroquinolone Products Liability Litigation,* Multi-District Litigation No. 2642 (the "Fluoroquinolone MDL"). (Notice of Transfer, Jan. 27, 2017, Docket No. 14.) Generic Defendants filed Answers on February 6, 2017. (Answer by Actavis, Feb. 6, 2017, Docket No. 19; Answer by Cobalt, Feb. 6, 2017, Docket No. 20.)

On February 27, 2017, Akman filed an Amended Complaint by completing the Fluoroquinolone MDL Short Form Complaint, which incorporates the allegations of the MDL Master Complaint ("Short Form Complaint"). (Am. Compl. ¶¶ 1, 15–16, Feb. 27, 2017, Docket No. 21.) In her Short Form Complaint, Akman alleged that she was injured by generic ciprofloxacin and that D.C. law supports her generics-related claim. (*Id.* ¶ 8.)

On July 31, 2020, Generic Defendants filed a Motion for Judgment on the Pleadings pursuant to Federal Rule of Civil Procedure 12(c), arguing that Akman failed to state a claim against them. (Mot. J. Pleadings, Jul. 31, 2020, Docket No. 29.) Akman asks the Court to grant leave to amend if the Court finds that the allegations pleaded in the Initial Complaint are insufficient to support her failure to update theory. (Pl.'s Mem. Opp. at 13, Aug. 21, 2020, Docket No. 34.)

DISCUSSION

I. STANDARD OF REVIEW

When evaluating the merits of a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), the Court applies the same legal standard that applies to a motion to dismiss for failure to state a claim under Rule 12(b)(6). *Ashley County v. Pfizer, Inc.*, 552 F.3d 659, 665 (8th Cir. 2009). As such, to survive a motion for judgment on the pleadings, a complaint must contain sufficient factual allegations to state a plausible claim for relief. *See Clemons v. Crawford*, 585 F.3d 1119, 1124 (8th Cir. 2009). A court accepts as true all facts pleaded by the nonmoving party and draws all reasonable inferences from the pleadings in favor of that party. *Id.* Without more, merely reciting the elements of a cause of action is insufficient, and legal conclusions asserted in the complaint are not entitled to the presumption of truth. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

A party may amend its pleading by leave of court, which "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a)(2). Amendment of pleadings is to be liberally allowed. *Thompson–El v. Jones*, 876 F.2d 66, 67 (8th Cir. 1989). Thus, "absent a good reason for denial—such as undue delay, bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the non-moving party, or futility of amendment—leave to amend should be granted." *Id.*

II. ANALYSIS

A. Operative Complaint

As an initial matter, the parties dispute whether the Court should consider the allegations in Akman's Initial Complaint since she had to file the Short Form Complaint after the case was transferred to the Fluoroquinolone MDL. Cases consolidated for multi-district litigation pre-trial proceedings ordinarily retain their separate identities. *Gelboim v. Bank of America Corp.*, 574 U.S. 405, 413 (2015). The individual pleadings do not merge if the master complaint is "not meant to be a pleading with legal effect," but rather is "only an administrative summary of the claims brought by all the plaintiffs." *Id.* at 413 n.3 (citation omitted). Additionally, "a court presiding over an MDL must take steps to ensure that efficiency does not trump fundamental fairness and that the desire for certainty does not deprive any individual party of substantive rights." *In re Gen. Motors LLC Ignition Switch Litig.*, No. 14-MC-2543, 2015 WL 3619584, at *1 (S.D.N.Y. June 10, 2015).

In this MDL, the Court has issued pretrial orders ("PTO") explaining that the short form complaint and incorporated master complaint should be filed rather than standalone complaints. Pretrial Order 1 states that "the [Plaintiffs' Steering Committee] also shall file . . . a Short Form Complaint, which shall be an abbreviated form that Plaintiffs will complete in lieu of filing standalone complaints." (PTO 1 at § 12.B, Feb. 12, 2016, MDL No. 15-2642, Docket No. 76.) Pretrial Order 3 likewise states that "[t]here

shall be a separate short form complaint filed for each individual plaintiff. No plaintiff shall file a non-short form complaint in this MDL." (PTO 3 at 5, Mar. 1, 2016, MDL No. 15-2642, Docket No. 95.) The master complaint, as incorporated in the short form complaint, is intended to have legal effect.

For Akman's case, however, the allegations and theories leveraged against the Generic Defendants, named in both the Initial Complaint and the Short Form Complaint,[2] would be lost if the Court disregards the contents of the Initial Complaint, since the Short Form Complaint and Master Complaint do not include allegations supporting claims directly against generic manufacturers of ciprofloxacin. Because the purpose of an MDL is to manage pretrial proceedings, not to eliminate the individual character of each case, the Court will address the Initial Complaint to determine whether Akman's proffered theory of liability is preempted by federal law.

B. Federal Preemption of State Law Claims

Akman's Initial Complaint asserts various tort and statutory claims under D.C. law against Generic Defendants based on the theory that they failed to update their product information after the FDA approved an updated warning for Cipro and its generic

[2] Defendants argue that they are not properly joined as Defendants in this case because they are not named in the Master Complaint. Akman named the Generic Defendants in the Initial Complaint and the Short Form Complaint in the space provided for litigants to identify "Other" defendants. As such, the Court finds that the Generic Defendants are properly parties to the action irrespective of which complaint is operative.

equivalent in August 2013. Generic Defendants argue that Akman's claims are preempted by federal law. The Supreme Court has issued two pivotal decisions about federal preemption of state law claims against generic drug manufacturers under the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act ("FDCA") based on impossibility preemption. Impossibility preemption exists where it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (quotation omitted).

In *PLIVA, Inc. v. Mensing*, the Supreme Court found that state law claims for failure to warn based on the inadequacy of a generic drug's labeling are preempted by federal law because "the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'" 564 U.S. 604, 613, 618 (2011). Claims asserting that generics should have stronger warnings, when their labels were the same as the brand-name counterpart, are preempted by impossibility because federal law prohibits a generic drug manufacturer from unilaterally strengthening the warnings on its product's labeling. *See id.* at 618. In *Mutual Pharm. Co. v. Bartlett*, the Supreme Court extended impossibility preemption under the FDCA to prohibit state law design defect claims against generic drug manufacturers because a generic drug manufacturer is prohibited from unilaterally redesigning its product. 570 U.S. 472, 483–84 (2013). In other words, pursuant to *Mensing* and *Bartlett*, plaintiffs cannot maintain claims that state law requires generic

drug manufacturers to provide stronger warnings or safer designs than their brand-name counterparts because complying with state law—i.e. providing a different warning or design than a brand-name—would result in violating the federal law duty of sameness.

The failure to update scenario presented by Akman differs from the claims in both *Mensing* and *Bartlett*. Akman asserts that, at the time she received the ciprofloxacin, the Generic Defendants' product information was not the same as the brand-name equivalent. Rather, the Generic Defendants failed to update their labels to match the brand-name after FDA approval of a new warning. Unlike *Mensing* and *Bartlett*, where the plaintiffs argued that state law required generic manufacturers to provide more warnings or implement a safer design for their generic drug than the brand-name drug, Akman argues that state law merely required Generic Defendants to match their labels to the FDA approved, brand-name version. Failure to update claims therefore can escape preemption under *Mensing* and *Bartlett* when compliance with federal and state duties is not only possible, but required. *See Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584 (6th Cir. 2013.) When it is possible for a generic manufacturer to provide a stronger warning without violating the FDA's duty of sameness and the generic manufacturer fails to do so, a narrow path around *Mensing* preemption exists. *See, e.g.*, *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 364 (Iowa 2014).

Failure to update claims are only viable, however, to the extent that a plaintiff was harmed by a generic manufacturer's failure to conform their product information with

the FDA-approved labeling. *See Fulgenzi*, 711 F.3d 578, 584 (holding that plaintiff's claims survive only to the extent that defendant's warning was inadequate because it did not include language from an updated FDA warning). The Fifth Circuit has expressed disapproval of failure to update claims in general, but particularly rejected the failure to update theory because "[t]ort liability does not arise from failure to attach an inadequate label." *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013). The Court agrees that a failure to update claim asserting that even the updated warning would have been inadequate is preempted because the generic manufacturer cannot unilaterally provide additional warnings under the duty of sameness. However, the Court disagrees that all failure to update claims are facially preempted, as it is possible to limit such claims to injuries caused by a generic manufacturer's failure to update their labels.

Even if a failure to update claim is not preempted by impossibility, it may nonetheless be impliedly preempted if a plaintiff merely seeks to enforce the FDCA through a private right of action. In *Buckman v. Plaintiffs' Legal Comm.*, the Supreme Court held that private plaintiffs cannot bring claims for violations of the FDCA that are not independently state law causes of action. 531 U.S. 341, 348 (2001). However, a state law claim survives when the claim is premised on conduct that both (1) violates the FDCA and is therefore not prohibited by impossibility preemption, and (2) would give rise to a recovery under state law even in absence of the FDCA and therefore is not impliedly

preempted under *Buckman. See Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

The Fifth Circuit rejected the failure to update theory on the ground that such claims are necessarily grounded in federal law, since they are about a federal labeling requirement. *Morris*, 713 F.3d at 777. Although some failure to update claims could be based only on federal law and therefore preempted, the Court finds that failure to update claims need not always be based on federal law. When a plaintiff can show that challenged conduct violates the FDCA, but the plaintiff is not suing simply because of the violation, the failure to update claim falls within the preemption gap. *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204–05 (8th Cir. 2010). Accordingly, a failure to update claim is not conclusively preempted.[3]

[3] The Eighth Circuit has not squarely held whether failure to update claims are preempted, although it has analyzed them based on the specific facts asserted, suggesting that such claims are not facially preempted. In *Fullington v. Pfizer, Inc*., rather than addressing the viability of the failure to update theory directly, the Eighth Circuit relied on the learned intermediary doctrine to conclude that the theory was immaterial because "[a] manufacturer's inadequate warning is not a proximate cause of a plaintiff's harm so long as the prescribing physician had independent knowledge of the risk that the inadequate warning should have communicated." 720 F.3d 739, 747 (8th Cir. 2013). The Eighth Circuit has relied on the learned intermediary doctrine to resolve failure to update-based cases on at least two other occasions. *See Brinkley v. Pfizer, Inc.,* 772 F.3d 1133, 1138 (8th Cir. 2014); *Bell v. Pfizer, Inc*., 716 F.3d 1087, 1098 (8th Cir. 2013). The Court takes note, therefore, that even though failure to update claims are not necessarily preempted, they may be difficult to prove on the merits, particularly in terms of causation between the label and injury.

In sum, if a plaintiff asserts a claim that (1) a generic drug manufacturer failed to update their labels to match an FDA-approved label adopted by brand-name manufacturers; (2) the claim is limited to the inadequacies of the non-updated label compared to the updated label; and (3) the claim is based on state law, such as common law negligence or a statutory duty, that would require generic manufacturers to update their labels irrespective of federal requirements, that claim is neither preempted by the FDCA under *Mensing* and *Bartlett* nor an attempt to assert a private right of action under the FDCA prohibited by *Buckman*.

C. Sufficiency of the Pleading

Because the Court finds that failure to update claims are not necessarily preempted by federal law, the Court must next determine whether Akman sufficiently pleaded such a claim. There are several reasons Akman's Initial Complaint fails to state a claim based on the failure to update theory.

First, the Initial Complaint is not limited to inadequacies in the drug warnings due to the failure to update. To fit within the preemption gap, Akman must allege liability only to the extent that she was injured by Generic Defendants' failure to update their labels to match the August 2013 FDA-approved version. *See Fulgenzi*, 711 F.3d at 584. Second, Akman's Initial Complaint does not tie Defendants' alleged liability for failure to update to D.C. law. As discussed above, to avoid preemption, a failure to update claim must be based on a state law duty for generic manufacturers to implement the latest FDA-

approved information. *See Riley*, 625 F. Supp. 2d at 777. Third, although the Initial Complaint does include allegations based on the failure to update theory, it also includes allegations that sound in traditional failure to warn liability which is preempted under *Mensing*, 564 U.S. at 618. It is unclear which causes of action are based on the non-preempted failure to update theory. In sum, the Court finds that Akman's Initial Complaint, as well as the Short Form Complaint, are insufficient and will grant Generic Defendants' Motion for Judgment on the Pleadings.

D. Leave to Amend

Akman asks the Court to grant leave to amend if the Court finds that she failed to state a claim based on her failure to update theory. *See Riley*, 625 F. Supp.2d at 785 (granting leave to file an amended complaint with the necessary detail to state a claim that is not preempted by the FDCA). The Court will grant leave to amend because it finds that amendment would not be futile, as there is a narrow path around federal preemption of state law claims against generic drug manufacturers. Further, Akman has not engaged in bad faith and amendment would not cause undue delay or prejudice to Defendants. *See Thompson–El*, 876 F.2d at 67. Finally, since this is the first opportunity for the Court to outline its views on the failure to update theory, the interests of justice are served by granting Akman an opportunity to conform her pleading to the requirements for a valid claim as described here. Accordingly, Akman shall file an amended complaint within 30 days of the entry of this Order.

Because Akman's case presents unique questions of law and fact as compared to other cases in the Fluoroquinolone MDL, the Court will determine whether it is the proper venue to hear the failure to update claims after Akman files an amended complaint. To assist the Court in determining whether this case should remain part of the Fluoroquinolone MDL, the parties shall submit supplemental briefing on the proper court of adjudication within 15 days of the filing of the amended complaint.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendants' Motion for Judgment on the Pleadings [Docket No. 29] is **GRANTED.**
2. Plaintiff's Complaint [Docket No. 1-1] and Short Form Complaint [Docket No. 21] are **DISMISSED WITHOUT PREJUDICE**.
3. Plaintiff is granted leave to file an amended complaint within 30 days of the entry of this Order.
4. Within 15 days from the filing of Plaintiff's amended complaint, both parties shall file memoranda addressing whether the case should be transferred back to the U.S. District Court for the District Columbia or continue as part of the Fluoroquinolone MDL.

DATED: November 4, 2020
at Minneapolis, Minnesota.

JOHN R. TUNHEIM
Chief Judge
United States District Court